SEP 26 2007

K070339

Page 1

PRE-MARKET NOTIFICATION 510(k) SUMMARY

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is: _____

GENERAL COMPANY INFORMATION AS REQUIRED UNDER 807.92 (A) (1)

Submitter's Name:
Cincinnati Sub-Zero Products, Inc
12011 Mosteller Road
Cincinnati, Ohio 45241-1528
Phone: 513-772-8810
Fax: 513-772-9119

Name of Contact Person:
Dan Wittmer, Engineering Manager
Date:
September 24, 2007

DEVICE NAME AS REQUIRED UNDER 807.92 (a) (92)

Trade Name:
Disposable Temperature Probes
Skin Temperature Sensor
Tympanic Temperature Sensor

Common name:
Temperature Probes

Classification Name:
The following class II classifications appear applicable:
FLL Clinical Electronic Thermometry 21 CFR 880.2910

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE {807.92(a) (3)}

The CSZ Disposable Temperature Probes/sensors and cables outlined above are substantially equivalent in materials, manufacturing, safety and effectiveness to the Predicate SMITHS Level 1 Temperature Probes and Cables:

SKIN TEMPERATURE SENSOR with the 400 series Thermistor Temperature Sensor (STS400)

TYMPANIC TEMPERATURE SENSOR with 400 series Thermistor Temperature sensor (TT400, TTSP-400, TTS-400J)

CABLES (C400-10, C400-10HP)

K070339

page 2

A DESCRIPTION OF THE DEVICE 807.92 (A) (4)

Undesirable effects of hypothermia and hyperthermia are clinically well documented. Malignant hyperthermia is every doctor's nightmare. To detect hypo/hyperthermia, the body temperature is continuously monitored using disposable temperature sensors or probes. The basic component of these sensors is a resistance chip, which is sensitive to changes in temperature. The chip is in the form of "400" series thermistor connected to a lead wire and encapsulated in a PVC cup. At the end of the lead wires an insert molded connector or standard phone connector provides for the interconnection with the instrument cable.

These sensors are inserted in the structure that fits specific anatomy where the temperature is measured.

The skin sensor is placed on the surface of the skin and is a part of the foam enclosure which provides thermal insulation for more accurate temperature measurement.

The tympanic probe is designed for placement in proximity to the tympanic membrane. The probe incorporates a small foam tip for atraumatic insertion and a large compressible foam cylinder for securement and thermal insulation.

The distal end of the skin sensor and the tympanic sensor is terminated with a Molex or phone connector for interconnection with the instrument cable.

The probes are individually packaged in sterilizable bags. There are 20 probes per box and 10 boxes per shipping carton. Probes are ethylene oxide sterilized.

The following probes and cables are included in this 510k application:

Probes:
- Skin Temperature Sensor (487M, 499B)
- Tympanic Temperature Sensor (495M, 495M-P)

Cables (4872MS, 4872ML, 4900B)

These probes can be used with Smith's Level 1 TM-200 temperature/monitors or any other multi-channel patient monitor compatible with the "400" series thermistors or equivalent.

The packaging label describes: the product name, catalog number, expiration date, CE mark, legal entity information and the caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

K070339
Pg 3

THE INTENDED USE {807.92 (a) (5)}

THE CSZ SKIN TEMPERATURE SENSOR is intended for use in routine continuous monitoring of skin temperature when the other sensors which might better reflect core body temperature are not clinically indicated. The sensor is designed for placement on the surface of the skin.

THE CSZ TYMPANIC TEMPERATURE SENSOR is intended for use in routine continuous monitoring of the tympanic temperature as an indicator of the core body temperature when this type of measurement is clinically indicated. The probe is designed for placement inside the ear canal.

All probes are intended for use by qualified medical professions only.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE 807.92 (a) (6)

The CSZ disposable temperature probes and cables are substantially equivalent in their intended use, accuracy, safety and effectiveness to the predicate Smith's Level 1 disposable temperature probes and cable (STS-400, TTS-400, C400-10 and C400-10HP)

The CSZ disposable temperature probes have the following similarities to the predicate disposable temperature probes:

- The intended use is the same
- The mechanical design suitable for measurements in different anatomical locations on the body is the same
- Mechanical design, materials, dimensions and manufacturing processes are equal
- Indications and contraindications are the same
- Thermistor's temperature/resistance curve and the accuracy within the measurement range are the same
- Methods of testing are the same
- Sterilization process are equal

The CSZ disposable temperature probes have the following differences from the predicated product:

- Labeling, artwork, logo and content of inserts

K070339

Pg 4

SUMMARY OF NON-CLINICAL TESTS WHICH SUPPORT A DETERMINATION OF SUBSTANTIAL EQUIVALENCE {807.92 (B) (2)}

In order to support the substantial equivalence status, the CSZ disposable temperature probes have been tested in the laboratory and have also been assessed against the standards as outlined below.

- Thermistor resistance/temperature curve and its accuracy. "400" series thermistor requirements
- Current leakage test (ICE601-1EN60601-1)
- Biocompatibility of materials in contact with body fluids (ISO 10993 Biological evaluation of Medical Devices
- IEC 60601-1:1988 & Amdt. 1:1991& Amdt. 2:1995 (part 1 General Requirements for Safety)
- IEC 60601-2-49:2001 (Part 2:-49 Particular requirements for the safety of multi-function patient monitoring equipment)
- EN12470-4:2001 Performance of electrical thermometers
- 21CFR Part 898, IEC 601-1 sub clause 56,3© Cables and cords 60227-1-7, 7,60245-1-8 60799
- ISO 15223:2000 Medical Devices-Symbols to be used with Medical Devices labeling and information to be supplied
- EN 980 + A1 + A2 graphical symbols for use in the labeling of medical devices
- ISO 14971:2000 Medical Devices – Application of risk management to medical devices
- 510(k) Sterility Review Guidance K90-1: Guidance for Industry and FDA, August 30, 2002

CONCLUSION

The above summary presents the evidence that the CSZ Disposable Temperature Probes (outlined above) are substantially equivalent in their design, intended use, accuracy of measurement, safety and effectiveness, to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2007

Mr. Dan Wittmer
Engineering Manager
Cincinnati Sub-Zero Products, Incorporated
12011 Mosteller Road
Cincinnati, Ohio 45241-1528

Re: K070339
Trade/Device Name: Skin Temperature Sensor, Catalog Numbers 487M and 499B
Tympanic Temperature Sensor, Catalog Numbers 495M and 495M-P
Instrument Cables, Catalog Numbers 4872MS and 4900B
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: August 24, 2007
Received: August 29, 2007

Dear Mr. Wittmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment C

Indications for Use

K070339

Device Name(s):

Skin Temperature Sensor, Catalog Numbers 487M and 499B

Tympanic Temperature Sensor, Catalog Numbers 495M and 495M-P

Instrument Cables, Catalog Numbers 4872MS and 4900B

Indications for Use:

Skin Temperature Sensor (487M and 499B): The CSZ skin temperature sensor is intended for use in routine continuous monitoring skin temperature when the other sensors which might better reflect core body temperature are not indicated clinically. The sensor is designed for placement on the surface of the skin.

Tympanic Temperature Sensor (495M and 495M-P): The tympanic temperature sensor is intended for use in routine continuous monitoring tympanic temperature as an indicator of core body temperature when this type of measurement is clinically indicated.

Instrument Cables (4872MS and 4900B): The intended use of the instrument cable is to interconnect the disposable temperature sensor/probe with the temperature monitoring instrument.

Prescription Use: XXXX and/or Over-the-Counter Use: _____

(Part 21CFR801 Subpart D) (Part 21CFR801 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070339